CURVED DILATOR AND METHOD

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Related Cases

[0001] This application claims priority to United States Provisional Patent Application entitled CURVED DILATOR AND METHOD, filed July 18, 2001, Serial No. 60/306,289 which is incorporated herein by reference.

Field of the Invention

[0002] The present invention generally relates to an instrument for dilating body tissue. More specifically, the present invention relates to an instrument that dilates the interspinous ligament which allows for precise initial placement of a trial sizing instrument or of an actual implant.

Background of the Invention

[0003] Typically, a physician will use a dilating tool to create and dilate an opening in tissue. Such a tool, however, may not be configured to be conveniently positioned relative to the surgical site.

Summary of the Invention

[0004] An embodiment of the present invention is a device for creating and dilating a hole in, for example, the interspinous ligament. The curved tip of the device has a range of dimensions so that a physician can also establish the diameter of the hole with the same device.

Brief Description of the Drawings

[0005] Figure 1 is a perspective view of an embodiment of the present invention;

[0006] Figure 2 is a perspective view of another embodiment of the present invention;

[0007] Figure 3 is a perspective view of yet another embodiment of the present invention;

[0008] Figure 4 is a perspective view of yet another embodiment of the present invention;

Detailed Description of the Invention

[0009] The device or curved dilator **100** creates and step or gradually dilates an opening in body tissue. In the preferred embodiment, the device **100** creates and step dilates an opening in the interspinous ligament. Referring to Figure 1, the device **100**

has an elongated body **102**, a handle **104** and a tapered curved tip **106**. The elongated body **102,** including the tapered curved tip **106,** is manufactured out of

material such as, but not limited to, titanium-6A1-4V EL1 alloy which conforms to ASTM Standard F136-96: Standard Specification Wrought Titanium 6 Aluminum 4 Vandium ELI (Extra Low Interstitial) Alloy (R56401) for surgical implant applications.

[0010] Implants are inserted between adjacent spinous processes to distract the spine segments and maintain them in a slightly flexed position to relieve symptoms of lumbar spinal stenosis and other conditions that cause pain which is associated with the back. Such implants have a spacer which remains in place between the adjacent spinous processes. The diameter of the spacer can vary to accommodate each patient.

[0011] An opening must be created in the interspinous ligament so that the implant can be inserted. The device **100** is used to step or gradually dilate the interspinous ligament and to confirm the correct implant size prior to its insertion. The curved tip **106** has a gradual taper with a first end **110** and a second end **108**. The diameter of the tapered curved tip **106** gradually increases from the first end **110** to the second end **108**. The diameter at the first end **110** and the second end **108** are preferably precisely machined to a known measurement. The device **100** can be marked so that the physician knows the range of diameters to which the device **100** was machined. For example, the handle **104** may be color coded, whereby a specific color correlates to a range of diameters or the largest diameter for a device **100**. The color coding on the handle **104** helps the physician quickly distinguish the difference between the various devices **100**.

[0012] A physician may have several of the devices **100, 200, 300, 400** (see Figures 1-4) so that he or she may create and further dilate an opening. For example, a first device **100** may have a tapered curved tip **106** where the first end **110** has a diameter of one millimeter and the second end **108** has a diameter of three millimeters. The second device **200** may have a first end **210** with a diameter of three millimeters and a second end **208** having a diameter of six millimeters (see Figure 2). The third device **300** may have a first end **310** with a diameter of six millimeters and a second end **308** having a diameter of nine millimeters (see Figure 3). The fourth device **400** may have a first end **410** with a diameter of nine millimeters and the second end **408** having a diameter of twelve millimeters (see Figure 4). One of obvious skill in the art will appreciate that these examples do not limit the possible ranges of diameters of the tapered curved tip **106, 206, 306, 406.** Even though several different dilators may be used, the rest of the application will refer to the device **100** as illustrated in Figure 1.

[0013] A physician can insert the first end **110** of first device **100** into the interspinous ligament to create an opening. By urging the curved tip **106** further into the interspinous ligament, up to the second end **108**, the opening is dilated to three millimeters. Generally an implant device has a spacer with a diameter larger than three millimeters, and thus the physician will remove the first device **100** from the opening and select a second device **200.** As the opening is at three millimeters, the physician should select a second device **200** where the first end **210** has a diameter of three millimeters and a second end **208** having a diameter of six millimeters. By inserting the second device **200** into the opening, the larger

diameter curved tip **206** will further dilate the opening. This process should continue until the diameter of the opening is substantially the same as the diameter of the device to be implanted within the patent. The diameter of the opening is the diameter of the curved tip **206**.

[0014] The device **100** can approach the interspinous ligament from one direction, through an incision. The tapered curved tip **106** is easily inserted into the spinous ligament. Typically, to insert an implant, a small incision is made while the patient is lying on his or her side. The curved tip **106** allows the physician to access the interspinous ligament through the small incision. By inserting the elongated body **102** into the incision, the physician can manipulate the curved tip **106** with the handle **104** and create an opening in the interspinous ligament with the curved tip **106**. Accessing the interspinous ligament through a single incision further minimizes damage to surrounding body tissue.

[0015] Accordingly, the invention of the device can be used for an inventive method of dilation. The method includes making an incision in the patient and inserting the curved tip **106** of the tool preferably perpendicular to the back in a direction from a posterior position to an anterior position. The tip**106** is then preferably inserted perpendicularly until it comes into the region above the interspinous ligament that is to be dilated. At that point, the tip **106** is substantially parallel to the ligament that is to be dilated. The handle of the device **100** would then be rotated and/or pivoted as the tip **106** is then urged into the interspinous ligament up to the second end **108**. The device **100** can then be removed. Should

further dilation be required, subsequent devices **100** with larger curved tips can be used.

[0016] The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Many modifications and variations will be apparent to practitioners skilled in the art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention with various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalents. The aspects, features, and advantages of the invention are also demonstrated in the figures and the claims.